

REMARKS

Claims 13-24 are all the claims pending in the application. Claims 13-24 presently stand rejected.

Claims 13-21 and 24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kambin (5,584,887) in view of McMillan (5,556,687).

Claim 22 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Kambin (5,584,887) in view of McMillan (5,556,687) and further in view of Törmälä et al. (5,084,051).

Claim 23 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Kambin (5,584,887) in view of McMillan (5,556,687) and further in view of Eisermann et al. (2002/0123750).

Analysis

Primary cited Kambin is only relevant to the present invention as background information for generally teaching a longitudinal implant and connecting device. This reference fails to disclose most of the important features of the invention including:

- (1) the longitudinal implant being made of a filament or fiber composite material, wherein filaments or fibers in the material are oriented to resist biomechanical forces,
- (2) a connecting device being made of a material harder than the longitudinal implant,
- (3) the connecting device being operative to squeeze and lock the longitudinal implant into position both by depression caused by squeezing and increased friction between the harder material of the connecting device and the composite material of the longitudinal implant, and
- (4) wherein the filaments or fibers are aligned lengthwise, so that compression will not change their strength characteristics to any extent even when compressed.

Thus, Kambin fails to teach or suggest any of the novel aspects of the invention which enable the connecting device to squeeze and lock the longitudinal implant into position by both of (1) depression caused by squeezing and (2) increased friction between the implant and connecting device. A stable connection is achieved from the friction and concave deformation of the material due to the particular structural configuration of the invention.

As discussed previously, the implant is softer and rougher than the connecting device, so that squeezing of the connecting device forms a concavity in the implant surface, and the surface friction of the implant prevents the connecting device from moving relative to the implant. These two features enhance the stability of the device.

This aspect of the invention is completely lost with the combination of references because there is no teaching or suggestion in either reference to have the depression and locking feature.

The Office Action asserts that Kambin is capable of squeezing and locking the longitudinal implant into position both by depression and squeezing.

Specifically, the Office Action states that the pressing of the connecting device 60 against the plate 82 by use of the nut 86 satisfies the depressing capability (see Office Action at page 6). However, the connecting device 60 is fixed to the plate 82 via the washer 84 and nut 86, wherein the washer 84 engages with the teeth formed along the outer edges of the plate. Although there may be some **pressure** caused by the engagement of these parts, there is **no depression** in the plate 82.

Likewise, McMillin is silent with regard to this feature. Instead, McMillin utilizes **pre-formed** spherical recesses to attain the locking position of the implant. That is, instead of

utilizing a depression formed by squeezing in the implant, pre-formed recesses are formed at the position in which the screws press on the implant.

In view of the foregoing, the combination of cited references fails to suggest a device capable of squeezing and locking an implant into position by depression caused by squeezing.

Still further, the Examiner relies on McMillin for modifying Kambin to utilize the composite materials of the present invention. The asserted motivation for modifying Kambin based on McMillin is “in order to allow the implant to resist splitting and resist bending...and the use of composite materials in a bone plate can be helpful in preventing stress shielding...”

Logically, this alleged motivation would have also included the spherical recess formation of McMillin which is specifically provided “to help prevent splitting of the plate” (col. 4, lines 23-27).

In other words, if the motivation to combine Kambin’s unrecessed longitudinal slot with the composite materials in McMillin is to resist splitting, one would have logically used the beveled formation also because McMillin teaches that the beveled slot helps keep the composite materials from splitting (col. 4, lines 10-27).

If the long list of proposed modifications based on a desire to “resist splitting” does not include the recesses, it seems the Examiner is merely picking and choosing certain features from McMillin to arrive at the claimed invention by using the Applicants’ disclosure as a roadmap.

The Office Action maintains (page 7) that because the spherical formation is not mentioned in the Summary section, and because it is only used as “helping to prevent splitting, but...not required to prevent splitting”, it is not a main component of the anti-splitting mechanism in McMillin.

However, every illustrative example of utilizing the composite materials in a bone plate includes the spherical recesses. That is, when the composite material is used in a bone plate to resist splitting, such a composite material has spherical recesses.

Still further, it is noted that the cited references are completely silent with regard to depressing the implant. While the structure of one device and the materials of another device are being piecemealed together to form the obviousness rejection, the combination of devices still fail to disclose depressions formed by squeezing.

It is not proper to dissect claims and reconstruct them in piecemeal fashion by picking and choosing from among the prior art references using the patent as a blueprint. *In re Kamm*, 452 F.2d 1052, 1056-57, 172 USPQ 298,301-02 (CCPA 1972). In determining obviousness, therefore, the inquiry is not whether each element existed in the prior art, but whether the prior art made obvious the invention **as a whole**. *Hartness Int'l, Inc. v. Simplimatic Eng'g Co.*, 819 F.2d 1100, 1108, 2 USPQ2d 1826, 1832 (Fed.Cir.1987).

Further, if prior art references require selective combination to conclude that an invention would have been obvious, there must be some teaching or suggestion in the references that would support their use in combination. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 293, 227 USPQ 657, 664 (Fed.Cir.1985), *cert denied sub nom.*, 475 U.S. 1017 (1986).

The locking feature caused by depressing and squeezing in Applicant's invention is attained by the combination of several structural features, including the shape of the implant slot (having no recesses), the relative hardness of the connecting device and implant, and the alignment of the filaments or fibers of the composite material. When all of these features are

combined, the squeezing and locking feature is attained. However, without the unique combination of these features, the squeezing and locking feature is lost. The Examiner chooses certain features of each of the references to argue that the squeezing and locking feature is obvious; however, without the teachings of Applicants own disclosure one would not have thought to have dissected the structure of the references to arrive at the locking invention. The prior art does not teach or suggest this locking invention *as a whole*.

Instead, in order to attain a locking function, one would have used the washer engaging with the toothed edges of Kambin, or the spherical recesses of McMillin. The combination of references, however, does not teach the locking feature of the claims which uniquely combine the lack of recesses, relative hardness, and depression formed in the implant.

Therefore, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of claim 13 because this claim is patentable over the combination of cited references.

The remaining rejections are directed to the dependent claims. These claims are patentable for at least the same reasons as claim 13, by virtue of their dependency therefrom.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

RESPONSE UNDER 37 C.F.R. § 1.116
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